DETAILED ACTION

Receipt is acknowledged of applicants' remarks and declaration, filed on 3 July 2008.

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Response to Amendment

The affidavit under 37 CFR 1.132 filed on 3 July 2008 is insufficient to overcome the rejection of claims 1 and 3-7 based upon the anticipation rejection in view of Oshlack and the rejection of claims 1 and 2 based upon the obviousness rejection in view of Oshlack as set forth in the last Office action because: the showing is not commensurate in scope with the claims. The declaration shows unexpected results based upon the process of making the product. However, the instant claims are product-by-process claims. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 3-7 remain rejected under 35 U.S.C. 102(a) as being anticipated by US 2002/0102302 ("Oshlack et al.").

Oshlack discloses a sustained release composition (*see* paragraph 0014) comprising:

- the double granule of instant claim 1 (*see* paragraph 0023)
- the tramadol of instant claim 3 (*see* paragraph 0014);
- the fatty acid ester of instant claim 4 (*see* paragraph 0056);
- the glyceryl monostearate of instant claim 5 (*see* paragraph 0056);
- the acrylic polymer of instant claim 6 (*see* paragraph 0060); and
- the additives of instant claim 7 (*see* paragraph 0021).

The process of preparing the sustained-release preparation disclosed in claim 1 is not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 2 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0102302 ("Oshlack et al.").

Oshlack discloses a sustained release composition (*see* above).

Oshlack differs from the instant application in that it does not explicitly teach the ranges of instant claim 2. However, the ranges disclosed by Oshlack overlap with those of claim 2.

Oshlack discloses: (a) a tramadol concentration of about 20-80%, (b) a hydrophobic material (e.g. fatty acid ester) concentration of about 20-80%, and (c) a hydrophobic polymer (e.g. acrylic polymer) concentration of about 0-80%. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 11/572,326 ('326). Although the conflicting claims are not identical, they are not patentably distinct from each other because '326 claims a sustained release pharmaceutical composition prepared by a first granulation method followed by a second granulation method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Response to Arguments

Applicants' arguments filed on 3 July 2008 have been fully considered but they are not persuasive.

35 USC 102

Applicants argue that Oshlack fails to teach double granules prepared by primary granulation of drug by melt granulation and secondary granulation by wet granulation using hydrophobic material. *See* remarks, page 3.

Examiner respectfully submits that Oshlack discloses double granules (*see* paragraph 0023). The process of making the double granules, as stated in the substantive rejection, is not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

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35 USC 103

Applicants repeat the argument that the instant application differs from the prior art by the method the making (*see* remarks, pages 3-5). As stated above, since the instant claims are product-by-process claims, the patentability of the claim depends on the product, not the method of production.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 8-13 drawn to an invention nonelected with traverse in the reply filed on 24 October 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615